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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/315,292	05/20/1999	CLARENCE FRANK BENNETT	ISIS-3561	6344
34138	7590	11/15/2005	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			BOWMAN, AMY HUDSON	
			ART UNIT	PAPER NUMBER

1635

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/315,292

Applicant(s)

BENNETT ET AL.

Examiner

Amy H. Bowman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 9/13/2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 6/14/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 9/13/05, claims 66-75 are pending in the application.

Response to Arguments--Claim Rejections - 35 USC § 112

Claim 72 stands rejected under 35 U.S.C. 112, second paragraph, for the reasons of record set forth in the office action mailed 6/14/05. It is noted that applicant has corrected claims 74 and 75, but has not corrected claim 72. Claim 72 recites the limitation "wherein said oligonucleotide is an aqueous media. It is unclear how the oligonucleotide itself can be an aqueous media. Appropriate correction is required. Amendment to recite, "wherein said oligonucleotide is in an aqueous media" would obviate this rejection.

Response to Arguments--Claim Rejections - 35 USC § 102

Claims 66 and 72-74 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kole et al. (US 5,627,274), for the reasons of record set forth in the office action mailed 6/14/05.

Applicant argues that the amendment to instant claim 66 reciting that the oligonucleotide is taken up by at least one cell type in the lung of a mammal should obviate this rejection. Applicant argues that Kole neither anticipates nor makes obvious the delivery of oligonucleotides to at least one cell type in the lung.

Applicant's arguments have been considered but are not found persuasive. Kole et al. teach a method of administering an oligonucleotide into a lung of a patient as a therapeutic in the treatment of disease, such as cystic fibrosis, via administering an aerosolized formulation of respirable particles to the lungs (see columns 5 and 6). Kole et al. teach formulations comprising the antisense oligonucleotide comprising sterile aqueous and non-aqueous solutions of the active compound, including saline or water. Kole et al. teach 2'-O-methyl modified oligonucleotides and teach that these modified oligonucleotides are resistant to nucleases and form stable hybrids with RNA that are not degraded by RNase H (see column 8). Kole et al. do not need to specifically exemplify these teachings in order for the teachings to be enabled. Kole et al. teach each of the method steps instantly claimed and therefore are as enabled as the instant claims. The elements of Kole et al. are instantly claimed, which are presumed to be enabled. The scope of the teachings of Kole et al. are directly commensurate with the scope of the instant claims. Since Kole et al. specifically teach method of administering

an oligonucleotide into a lung of a patient as a therapeutic in the treatment of disease via administering an aerosolized formulation of respirable particles to the lungs, the oligonucleotides of Kole et al. would necessarily be taken up by a cell in the lung. As evidenced by the 1.132 declaration submitted by applicant, these same method steps result in oligonucleotide uptake to at least one cell type in the lung. Therefore, the instant invention is anticipated by Kole et al.

Claims 66-68 and 70-75 stand rejected under 35 U.S.C. 102 (e) as being anticipated by Baracchini et al. (US 5,801,154), for the reasons of record set forth in the office action mailed 6/14/05.

Applicant argues that the amendment to instant claim 66 reciting that the oligonucleotide is taken up by at least one cell type in the lung of a mammal should obviate this rejection. Applicant argues that Baracchini does not teach delivery to at least one cell type in the lung. Applicant argues that Baracchini neither anticipates nor makes obvious the delivery of oligonucleotides to at least one cell type in the lung.

Applicant's arguments have been considered but are not found persuasive. Baracchini et al. teach antisense oligonucleotide delivery via inhalation or insufflation and formulations including sprays (see column 4). Baracchini et al. teach methods of treating animals suspected of having a condition such as lung cancer comprising administering antisense oligonucleotides (see claims 26 and 29). The methods taught by Baracchini et al. are considered to be as enabled as applicant's instant specification. Additionally, Baracchini et al. teach that oligonucleotides with at least one 2'-

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methoxyethyl modification are believed to be particularly useful for oral administration (see column 4). Baracchini et al. specifically teach 2'-O-methoxyethyl modifications, 2'alkoxyalkoxy modifications, non-phosphorous containing linkages, as well as phosphorothioate modifications (see columns 6-8). Baracchini et al. teach that such modifications increase resistance to nucleases. The oligonucleotides taught by Baracchini et al. are administered in aqueous media including sterile water, saline solution, or powders. Baracchini et al. do not need to specifically exemplify these teachings in order for the teachings to be enabled. The elements of Baracchini et al. are instantly claimed, which are presumed to be enabled. Baracchini et al. teach each of the method steps instantly claimed and therefore are as enabled as the instant claims. The scope of the teachings of Baracchini et al. are directly commensurate with the scope of the instant claims. Since Baracchini et al. specifically teach methods of treatment via administering antisense oligonucleotides and further teach that inhalation or insufflation are acceptable means of delivery, the oligonucleotides of Baracchini et al. would necessarily be taken up by a cell in the lung. As evidenced by the 1.132 declaration submitted by applicant, these same method steps result in oligonucleotide uptake to at least one cell type in the lung. Therefore, the instant invention is anticipated by Baracchini et al.

Claims 66-75 stand rejected under 35 U.S.C. 102 (e) as being anticipated by Bennett et al. (US 5,955,443), for the reasons of record set forth in the office action mailed 6/14/05.

Applicant argues that the amendment to instant claim 66 reciting that the oligonucleotide is taken up by at least one cell type in the lung of a mammal should obviate this rejection. Applicant argues that Bennett does not teach delivery to at least one cell type in the lung. Applicant argues that Bennett neither anticipates nor makes obvious the delivery of oligonucleotides to at least one cell type in the lung.

Applicant's arguments have been considered but are not found persuasive. Bennett et al. teach antisense oligonucleotide delivery via aerosols and formulations including sprays. Bennett et al. teach methods for the treatment and diagnosis of mammalian diseases. The methods taught by Bennett et al. are considered to be as enabled as applicant's instant specification. Bennett et al. specifically teach 2'-O-methoxyethyl modifications, 2'-alkoxyalkoxy modifications, a 2'-O-diakylaminooxyalkyl substituent that is 2'-dimethylaminooxyethoxy in order to enhance the affinity of an antisense oligonucleotide for its target nucleic acid, non-phosphorous containing linkages, as well as phosphorothioate modifications. Bennett et al. teach that such modifications increase resistance to nucleases. The oligonucleotides taught by Bennett et al. are administered in aqueous media including sterile water, saline solution, or powders. Bennett et al. do not need to specifically exemplify these teachings in order for the teachings to be enabled. Bennett et al. teach each of the method steps instantly claimed and therefore are as enabled as the instant claims. The elements of Bennett et al. are instantly claimed, which are presumed to be enabled. The scope of the teachings of Bennett et al. are directly commensurate with the scope of the instant claims. Since Bennett et al. specifically teach methods of treatment via administering antisense

oligonucleotides and further teach that the oligonucleotides can be delivered via aerosols and formulations including sprays, the oligonucleotides of Bennett et al. would necessarily be taken up by a cell in the lung. As evidenced by the 1.132 declaration submitted by applicant, these same method steps result in oligonucleotide uptake to at least one cell type in the lung. Therefore, the instant invention is anticipated by Bennett et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

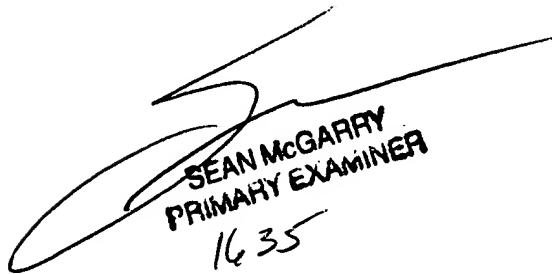
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Amy H. Bowman
Examiner
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SEAN MCGARRY
PRIMARY EXAMINER
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